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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,265	05/04/2007	Volker Bodecker	MED5001	6589

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EXAMINER	
STOUT, MICHAEL C	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,265	BODECKER ET AL.	
	Examiner	Art Unit	
	MICHAEL C. STOUT	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-16 and 18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/10/2009 has been entered.

Claim Objections

Claim 15 is objected to because of the following informalities: Claim 15 is an improper dependent claim and is dependant upon a canceled claim, the limitation is addressed in claim 1. Appropriate correction is required.

Claim 15 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 recites the limitation of an angle from 60 to 120 degrees.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 3-6, 8-15, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brehmeier-Flick et al. (US 6083174) in view of Jeffries et al. (US 6193656) and B-Flick et al. "Study and Development of a Portable Telemetric Intracranial Pressure Measurement Unit." 19th International Conference Proceedings, IEEE/EMBS Oct. 30 – Nov. 2, 1997 Chicago, IL USA.

Regarding **claim 1** Brehmeier-Flick discloses an implant comprising a sensor device (sensor element 1,see Column 4, Line 19) being fixedly connected to a first end of a longitudinal carrier (flexible foil 3, see Column 4, Line 20 and Figure 1); and an inductive coil (telemetry unit 2, see Column 4, Line 22) connected to the sensor device via electrical connection lines (strip conductors 4, see Column 4, Line 20) that are arranged on the longitudinal carrier; a covering encapsulating the sensor device (layer 6b, See Column 4, Line 39), the carrier with the connection lines (layer 6a, See Column 4, Line 37), and the coil (6c, See Column 4, Line 39) ; wherein the carrier has a sufficient rigidity such that the sensor device is adapted to be guided by the carrier during implantation to a target position and held in position at the target position (the flexible foil 3 is easy to implant because it can be slid under the skin without twisting or being moved in a undesirable direction, see Column 4, Lines 24-27, Figure 2 shows the flexible foil 3 which a sensor and telemetery unit 2 arranged thereon along with strip conducts, the sensor and telemetry unit each have a protective layer of 6b and 6c respectively, Figure 2 which is a cross -section view of the implant in Figure 1 shows the foil having a rectangular cross section see Figure 2, and furthermore Figures 1 and

2 combined show a foil 3 comprising a rectangular cross section along the shortest with dimension shown in Figure 1).

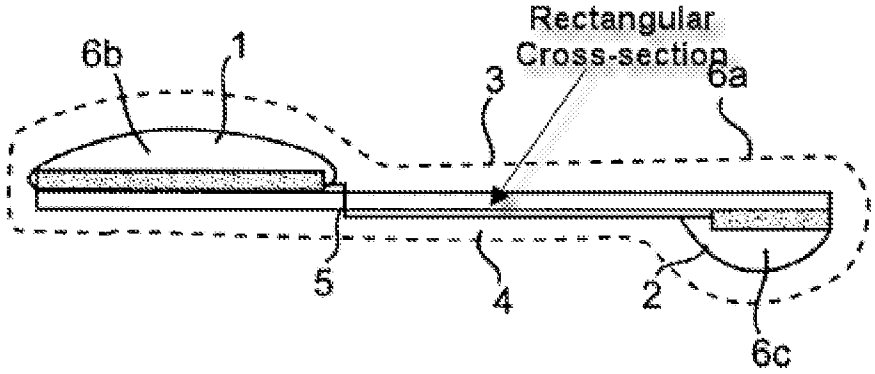

FIG. 2

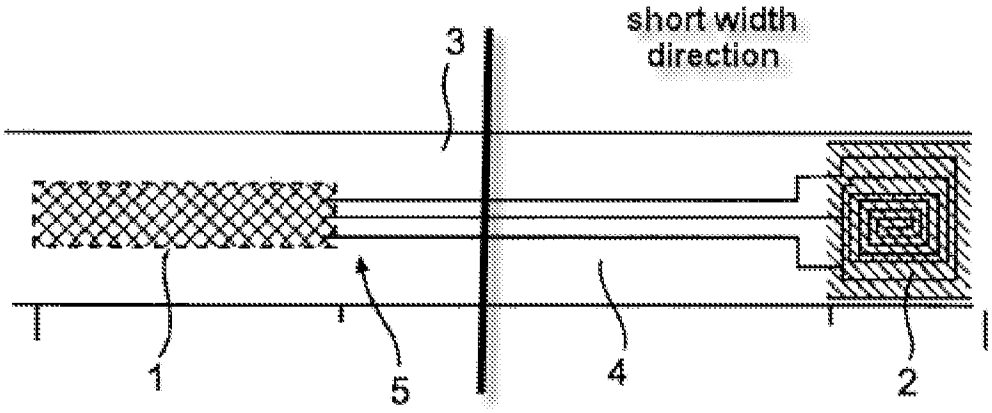

FIG. 1

Brehmeier-Flick teaches the device wherein the carrier is formed of a thin flexible film which is rod-shaped with a rectangular cross-section, see Figures 1 and 2 above, wherein the carrier is substantially planer shape (Figures 1 and 2) and is bendable from

said planar shape to a shape wherein the carrier is arranged at an angle relative to the plan in which the coil windings of the inductive coil are arranged (the film is flexbile and capable of bending such that the carrier is arranged at an angle to the coils 2). While Brehmeier-Flick fails to explicitly state the carrier being capable of being bent at an angle of 60 to 120 degrees, one of ordinary skill in the art at the time of the invention would recognize that the flexible film taught by Brehmeier-Flick is capable of being bent at an angle within the claimed range relative to the coil windings.

The Applicant's specification attributes this capability to the construction of the carrier, "The carrier may for example be formed as thin polyimide foil which for stiffening may comprise a cambered form. The carrier may also be rod-shaped with a rectangular cross-section or a circle segment cross-section."

As mentioned above Brehmeier-Flick teaches a rod-shaped foil with a rectangular cross section. Brehmeier-Flick fails to teach the carrier material.

B-Flick teaches the carrier material is polimide tape, See Page 978, Paragraphs 1-3.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the device taught by Brehmeier-Flick to include a poyimide carrier as taught by B-Flick in order to provide a biocompatible substrate for mounting the sensor and coil component.

Brehmeier-Flick fails to disclose a device wherein the covering part has means for subcutaneous fastening. Jeffries teaches an implant comprising a covering part

(housing 500, see Figures 5-8) having a means for subcutaneous fastening (eyelets 502 and 504, see Figure 5).

Both Brehmeier-Flick and Jeffries teach implant devices. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device disclosed by Brehmeier-Flick to include have a means for subcutaneous fastening as taught by Jeffries in order to connect the sensor to a site in the body, see Jeffries Column 2, Lines 25-33.

Regarding **claim 3,** Brehmeier-Flick further discloses a device wherein there are provided two connection lines between the coil and the sensor device (see Figure 1).

Regarding **claim 4,** Brehmeier-Flick further discloses a device wherein the carrier is flat (see Figure 2).

Regarding **claims 5-6,** Brehmeier-Flick further teaches a device further comprising a stiffening foil being provided in the covering part (the flexible foil while being the carrier also provides stiffening for successful implantation, see Column 4, Lines 24-27) and the carrier is formed as a foil (flexible foil 3) .

Regarding **claim 8 and 9,** Brehmeier-Flick further discloses a device wherein a frame formed in one piece with the carrier (area of the carrier immediately surrounding the sensor, see Figure 1) is fastened at the first end of the carrier, the sensor device positively fits within the frame (the sensor device fits within the frame area of the carrier, see Figure 1).

Regarding **claim 10,** Brehmeier-Flick further discloses a device wherein the carrier is formed as a common carrier (all of the components are arranged on the

flexible foil 3, see Column 4 Lines 19-21 and Figure 2) for the electrical connection lines and the coil windings.

Regarding **claim 11,** Brehmeier-Flick further discloses a device wherein the sensor device comprises at least one pressure sensor (see Column 4, Lines 7-18).

Regarding **claims 12, 13, 14,** Brehmeier-Flick further discloses a device wherein the covering part encapsulating the coil is adapted to be arranged in an interior of the brain, (the covering part 6a is made of silicone, a pressure transmitting medium, Column 4 Lines 32-39) and is equipped with a pressure capable of providing at least one of an intraparenchymal and intraventricular pressure measurements once positioned in an interior of the brain, see also Column 1, Lines 39-56.

Regarding **claim 15**, see claim 1 above.

Regarding **claim 16** Brehmeier-Flick further discloses a device wherein the covering part encapsulating the coil is adapted to be arranged in the epidural (the covering part 6a is made of silicone, a biocompatible material, see Column 4, Lines 32-39 and Column 1, Lines 39-56).

Regarding **claim 18** Brehmeier-Flick/B-Flick teaches the implant of claim 13, wherein the carrier is bendable substantially about a line adjacent to said inductive coil (Brehmeier-Flick/B-Flick teaches a rectangular flexible foil formed from polyimide and having a rectangular cross section which is capable of being bent adjacent to the inductive coils).

Response to Arguments

Applicant's arguments with respect to claims 1, 3-6, 8-16 and 18 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant's arguments are directed towards newly presented claim language which is addressed in the office action above. The claim limitations regarding the carrier being bendable are directed towards the intended use of the device, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736